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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAR 31 2003

WARNING LETTER

VIA FEDERAL EXPRESS

President/Owner
Cherokee Naturals, Inc.
10010 Highway 92
Suite #110
Woodstock, Georgia 30188

Ref. No: 03-HFD-312-10

Dear Sir or Madam:

This letter is written in reference to your firm's marketing of various products that are promoted on your Internet web site, www.herbshop.com, as alternatives to illicit street drugs. Some of these products purport to contain sources of ephedrine (i.e., ephedra, ma huang, or sida cordifolia).

Your Internet web site, from which these products may be ordered, promotes these products with brand names and claims, indicating that they are intended to be used as street drug alternatives, and lists ingredients of these products, as follows:

- **Organic Ecstacy tablets**

  "Experience an all natural 100% vegetarian buzz. An herbal mind expanding euphoria. From themakers [sic] of Herbal Ecstacy (which is no longer being produced under agreement with the F.D.A.) comes new Organic Ecstacy."

- **Space Cadets capsules**

  "Travel to another dimension. Ingredients: Ipomoea convolvulaceae, Argyria nervosa, Sida cordifolia extract, Paulina cupana extract, Gamma Amino Butyric Acid, gelatine [sic] (capsules.)"

- **Druids Fantasy capsules**

  "Psychedelic ... Time to Fly[.] Ingredients: Ipomoea convolvulaceae, Argyria nervosa, Acoru calamus extract, Piper methysticum extract, gelatine [sic] (capsules.)"

- **Bliss Extra capsules**

  "Super Ecstatic Sensory Overload[.] Ingredients: Sida cordifolia extract, Acoru calamus extract, Ipomoea convulaceae, Eleutherococcus senticosus extract, Gamma Amino Butyric Acid, L-Taurine, Paullina cupana extract, gelatine [sic] (capsules.)" In addition to the claim associated with this product, the product's label includes an oversized "X," suggesting that it is an alternative to the illicit street drug ecstacy.

FDA is aware that some street drug alternatives are being marketed as dietary supplements. FDA does not believe that street drug alternatives are intended to be used to augment the diet to promote health or reduce the risk of disease. Accordingly, street drug alternatives are not intended to supplement the diet and are not dietary supplements. In March of 2000, FDA made available a guidance for industry on street drug alternatives. This document contains additional information and is available at http://www.fda.gov/cder/guidance/index.htm.

Based on the claims cited, the products discussed above are "drugs" as defined in Section 201(g) of the Federal Food, Drug, and Cosmetic Act (Act). Moreover, they are also "new drugs" (Section 201(p) of the Act) because there is no evidence that these products are generally recognized as safe and effective for their intended uses. Under Section 505 of the Act, a new drug may not be introduced or delivered for introduction into interstate commerce unless an FDA-approved new drug application (NDA) is in effect for such drug. Since these products are not the subjects of approved NDAs, they may not be marketed in the United States and their continued marketing violates Section 505 of the Act.

This letter is not intended to be an all-inclusive review of your Internet web site or all of your firm's labeling and products, and it is not intended to be an all-inclusive list of violations concerning your firm and its products. You are responsible for ensuring that all products marketed by your firm are in compliance with applicable United States laws.

We request that you take prompt action to correct these violations. Failure to promptly correct violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug, and Cosmetic Act provides for seizure of illegal products and for an injunction against the manufacturer and/or distributor of illegal products.

You must notify this office in writing within fifteen (15) working days of your receipt of this letter as to the specific actions you have taken to correct the stated violations. You should also include an explanation of each step you have taken to assure that similar violations will not recur. If corrective action cannot be completed within 15 working

days, state the reason for the delay and the time within which the corrections will be made. Further, if your firm does not manufacture the product, your reply should also include the name and address of the manufacturer. If the firm from which you receive the product is not the manufacturer, please include the name of your supplier in addition to the manufacturing firm.

Address your reply to the Food and Drug Administration, Division of New Drugs and Labeling Compliance, 5600 Fishers Lane, (HFD-310 / MM2 / Rm. 328), Rockville, MD 20857, Attention: Dr. Linda Silvers.

Sincerely,

David J. Horowitz, Esq.
Director
Office of Compliance
Center for Drug Evaluation and Research

cc:
Hostmaster, RegisterWizards.com
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San Diego, California 92154